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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,016	05/31/2005	Dong-Hyun Kim	7260P001	8746

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EXAMINER

CLARK, AMY LYNN

ART UNIT

PAPER NUMBER

1655

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/511,016

**Applicant(s)**

KIM ET AL.

**Examiner**

Amy L. Clark

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 4 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- Paper No(s) Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s) Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Acknowledgment is made of the receipt and entry of the amendment filed on 2 April 2008 with the cancellation of Claims 13-16 and the amendment of claims 1 and 17.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 April 2008 has been entered.

**Claims 1, 2, 4 and 17 are currently pending and are currently under examination.**

#### ***Claim Rejections - 35 USC § 103***

Newly amended claims 1, 2, 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonoda (N, JP 08-196269 A, Translation provided herein), in view of Okawa (O, JP 08-092114 A, Translation provided herein), Chin et al. (P\*, JP 07-089863 A) and Shibata (U\*, "Chemistry and Cancer Preventing Activities of Ginseng

Saponins and Some Related Triterpenoid Compounds," J. Korean Med. Sci. Vol 16 (Suppl) (2001) 28-37).

Sonoda teaches a method of obtaining saponins by culturing a callus of medicinal ginseng. Sonoda further teaches a primary culture medium suitable for proliferation of the callus and a secondary culture medium capable of promoting the production of saponin are used as the culture medium prepared by adding naphthaleneacetic acid as a plant growth regulator to a basal culture medium and the secondary culture medium is a culture medium obtained by adding gibberellin as a plant growth regulator to the basal culture medium; therefore, the production amount of the saponin can be increased without complicating the composition of the culture medium. Sonoda further teaches that the saponin is the same medicinal properties as a natural medicinal ginseng. Sonoda further teaches that acetic acid is added to the agar culture medium. Sonoda further teaches after culture, it is freeze-dried, washed with water washed, and freeze dried. Sonoda further teaches the extraction method of saponin is as follows. The mortar ground the freeze-dried callus and methanol is added twice and the methanolic extract was obtained. This was dissolved in 50 ml of demineralized water, it put into the separating funnel, and 50 ml of ether washed twice. 50 ml of water saturation n-butanol extracted the water layer (lower layer) twice with n-butanol saturated water further, and the water saturation n-butanol layer (upper layer) was obtained and that the crude saponin was obtained for this solvent distilling out and by carrying out reduced pressure drying.

Sonoda does not teach lactic acid bacteria; however, Okawa teaches a method of obtaining saponins from ginseng comprising the steps of inducing a callus from medicinal ginseng, wherein the medicinal ginseng is *Panax ginseng* and wherein the callus is grown on a culture medium. Okawa further teaches that a microorganism or its extraction ingredients, such as bacteria can be added to the mass culture. Okawa further teaches that obtaining the cultured cell system which has high propagation activity from a medicinal ginseng radix plant body by the above-mentioned tissue culture method, and produces saponin, that the saponin can be used as foodstuffs, a crude drug, or a medicine raw material.

Chin teaches a method of making a food comprising ginseng inoculated with lactobacillus, which is a type of lactic acid bacteria, at a pH of 4.0 or higher (See page 4), wherein an extract of ginseng may be made from the stems of Siberian ginseng, roots of other ginsengs, such as Asian ginseng, American ginseng, or tissue cultures from Asian ginseng, American ginseng, Siberian ginseng, *Panax japonicas*, or *Panax notoginseng* (See pages 4 and 5). Chin further teaches that the ginseng may be extracted with aqueous alcohol (which reads on organic) following shredding, crushing or grinding the ginseng, and subsequently drying the solution under vacuum to provide ginseng to a condition to add to the lactobacillus (See page 4). Chin further teaches that dried ginseng may be extracted with ethanol, which is an organic solvent (See page 13, Example 16). Chin further teaches that after fermentation with lactobacillus, a supernatant is obtained that contains ginenosides (which reads on saponins) and that

the supernatant may be dried (See page 8) and that the supernatant may be subjected to chromatography to provide a purified saponin (See page 11).

Sonoda does not teach *Bifidobacterium*; however, Shibata discloses that ginsenosides are obtained by acid treatment using ginseng extracts (page 30, paragraph 1). Shibata further teaches that the ginsenosides were subjected to incubation with human intestinal flora, *Bifidobacterium* and *Fusobacterium* K-60 (See page 31, paragraphs 3 and 4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of preparing a pharmaceutical composition taught by Sonoda to provide the instantly claimed invention because at the time the invention was made, the method steps of treating ginseng with citric acid, extracting the treated ginseng with an organic solvent, fermenting the extracted ginseng with lactic acid bacteria, isolating saponins and drying the organic extract were known in the art, as clearly taught by Sonoda, Okawa, Chin and Shibata.

Finally, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to combine the method steps taught by each of the abovementioned references because at the time the invention was made, treating ginseng with citric acid, extracting an organic from ginseng with methanol to obtain saponins, as clearly taught by Sonoda, as was a method of obtaining saponins from ginseng comprising adding bacteria to the abovementioned steps, as clearly taught by Okawa, as was a method of fermenting an organic extract of ginseng with lactic acid bacteria, as clearly taught by Chin, as was that *Bifidobacterium* is useful for fermenting

ginseng to obtain saponins, as clearly taught by Shibata.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 103***

Applicant's arguments with respect to the rejection of claims 1, 2, 4 and 17 under 35 U.S.C. 103(a) as being unpatentable over Chin et al. (P\*, JP 07-089863 A), in view of Ishida et al. (Q\*, JP 63-216432 A), Tsuji et al. (R\*, JP 2001-112437 A), Shibata (U\*, "Chemistry and Cancer Preventing Activities of Ginseng Saponins and Some Related Triterpenoid Compounds," J. Korean Med. Sci. Vol 16 (Suppl) (2001) 28-37), Bae et al. (V\*), Roberfroid (W\*), Hikino et al. (S\*, JP 61-115013 A), Hashimoto et al. (T\*, JP 03-277247 A), and [http://web.archive.org/web/\\*/http://www.diabetic-lifestyle.com/articles/mar00\\_cooki\\_1.htm](http://web.archive.org/web/*/http://www.diabetic-lifestyle.com/articles/mar00_cooki_1.htm) (X\*) have been considered but are moot in view of the new ground of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-

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1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark  
AU 1655

Amy L. Clark  
June 19, 2008

/Michele Flood/  
Primary Examiner, Art Unit 1655